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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,879	12/30/2004	Anthony Devasia Joseph	13473.0006USWO	7399
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MERCHANT & GOULD PC			WINSTON, RANDALL O	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/519,879	JOSEPH, ANTHONY DEVASIA	
	Examiner Randall Winston	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 April 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
  - 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1204</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-7 and the election of species of *Semecarpous Anacardium Linn* in its response to the restriction requirement of 04/09/2007 is acknowledged. The traversal is based on claims 1-7 refer to class 424 and constituents used fall under subclass 754. Claims 8-11 are also drawn to process which falls under class 424 where the constituents fall under subclass 754 and subclass 756 as set out in claim 8. In view of the above, applicants respectfully request the examiner to withdraw the restriction. Moreover, applicants argue the nuts fall under the anacardiaceae family, and a literature search would be for inventions in the field of ayurveda where in nuts from the anacardiaceae family are used along with extract of allium sativum linn and zingiber officinale linn. Accordingly, it would not be an undue burden to search both of the species listed in the species election requirement.

Applicant's argument is not found persuasive because, as Examiner explained in the previous restriction requirement of 02/05/2007, the inventions are distinct if either or both of the following can be shown (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process of producing an ayurvedic preparation such as in Patent Application No. 1184/MUM/2001 (i.e. see e.g. applicant's specification on page 1 lines 8-15). Thus, the several inventions above are independent and distinct, each from the other. They have

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acquired a separate status in the art as separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

Moreover, although applicant's argue that it would not be an undue burden to search both species together listed in the species election requirement, applicant's argument is not found persuasive because the species are independent and distinct and/or mutually exclusive from each other because the claimed species are of different structures which requires a different search for each structure. Furthermore, Applicant has not demonstrated that the species are not patentably distinct and applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. Therefore, a search of all the claimed species would impose a serious burden on the Office because Applicant has not demonstrated that the claimed species are not patentably distinct structures.

The restriction requirement and the election of species requirement are still deemed proper and are therefore made final.

Claims 8-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 1-7 will be examined on the merits.

### ***Claim Objections***

Claims 1,2,5 and 6 are objected to because of the following informalities: In claims 1,2,5 and 6 the Latin names of (*Anacardiaciae*, *Allium Sativum Linn*, *Zingiber Officinale Rose Linn*, *Semecarpous Anacardium Linn* and *Anacardium Occidentale Linn*) should be italicized. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 are rendered vague and indefinite because of the term "nutrioinal". It appears to examiner that the above term is misspelled. The correct term should be nutritional. Correction is required.

Claim 1 step b is rendered vague and indefinite because of the phrase "an extract of *Allium Stavum Linn-Zingiber Officinale Rose Linn*." It appears to examiner by interpreting the above phrase that applicant is claiming only one extracted species

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instead of two separate extracted species. Is applicant claiming two separate species such as *Allium Stavum Linn* and *Zingiber Officinale Rose Linn*? It appears to examiner by interpreting claim 5 that applicant is claiming two separate species. Clarification is required.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 USC 112, first paragraph, because the specification, while enabling for a composition consisting essentially of nut oil extract obtained from nuts from the plant species of *Semecarpous Anacardium Linn* or *Anacardium Occidentale Linn* and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed disorders therein, the specification does not enable any person in the art in preparing a composition consisting essentially of nut oil extract obtained from nuts from the entire *Anacardiaceae* genus and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed disorders therein; nor does the specification enable any person in the art to prepare a composition for the use as a prophylactic (i.e.

preventing) for the claimed disorders therein. The specification does not enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition consisting essentially of nut oil extract obtained from nuts from the entire *Anacardiaceae* genus and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed disorders therein. Applicant has reasonably demonstrated on pages 3-5, especially on page 3 lines 12-26 of the specification, a composition consisting essentially of nut oil extract obtained from nuts from the plant species of *Semecarpous Anacardium Linn* or *Anacardium Occidentale Linn* and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed disorders therein. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a composition consisting essentially of nut oil extract obtained from nuts from the entire *Anacardiaceae* genus and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed

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disorders therein. Moreover, applicant claims a composition for the use as a prophylactic (i.e. preventing) for the claimed disorders therein consisting essentially of the claimed active ingredients therein. Please note the term prevent and/or prophylactic is an absolute definition which means to stop occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has reasonably demonstrated on pages 3-5 of the specification, a composition for the treatment of the claimed disorders (i.e. for the treatment of cardiac ailments and for increasing cardiac muscle tonicity) consisting essentially of the claimed active ingredients therein. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a composition for the use as a prophylactic (i.e. preventing) for the claimed instant disorders consisting essentially of the claimed active ingredients therein. Accordingly, it will take undue experimentation without reasonable expectation of success for one skill in the art to prepare a composition for the use as a prophylactic (i.e. preventing) for the claimed disorders consisting essentially of the claimed active ingredients therein.

Furthermore, it should be noted that the state of the prior art at the time the invention was filed did not recognize a composition consisting essentially of nut oil extract obtained from nuts from the entire *Anacardiaceae* genus and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn* to treat the claimed disorders therein such as cardiac ailments and for increasing cardiac muscle tonicity. For example, Shimomura et al. teach (see, e.g. JP404089419A, abstract) a cashew nut oil (i.e. cashew nuts are *Anacardium Occidentale Linn*) that has antioxidative and

antimicrobial action for excellent beautifying effects. Thus, the art is silent regarding the efficacy of applicant's composition consisting essentially of nut oil extract obtained from nuts from the entire *Anacardiaciae* genus and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed cardiac ailments and for increasing cardiac muscle tonicity. Therefore, applicant's claimed composition consisting essentially of nut oil extract obtained from nuts from the entire *Anacardiaciae* genus and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed disorders therein is unpredictable in the art. In addition, applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a composition consisting essentially of nut oil extract obtained from nuts from the entire *Anacardiaciae* genus and further including the other claimed extracts (i.e. *Allium Sativum Linn* and *Officinale Rose Linn*) to treat the claimed disorders therein.

Therefore, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope with the claims.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. (JP 04089419, see abstract) in view of Matsutani et al. (US 6444651) and Rosenstiel (US 6607756).

Applicant claims a composition consisting essentially of nut oil extract obtained from nuts from the plant species of *Semecarpous Anacardium Linn* or *Anacardium Occidentale Linn* and further including the other claimed extracts of *Allium Sativum Linn* and *Officinale Rose Linn*.

Shimomura teaches a nut oil extract obtained from the nuts from the plant species of *Anacardium Occidentale Linn* (i.e. *Anacardium Occidentale Linn* is cashew nut shell oil whereas cashew nuts are food products that can be taken orally) having antioxidant and/or antimicrobial activity. Shimomura, however, does not teach the other claimed active ingredients of *Allium Sativum Linn* (i.e. well known as garlic) and *Officinale Rose Linn* (i.e. well known as ginger) having antioxidant and/or antimicrobial activity. (see, e.g. abstract).

Matsutani beneficially teach garlic having antimicrobial activity. (see, e.g. column 1 lines 15-26

Rosenstiel beneficially teach ginger having antioxidant and/or antimicrobial activity. (see, e.g. column 3 lines 36-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Shimomura's composition teachings to include the active ingredients of garlic and ginger as taught by Matsutani and Rosenstiel within Shimomura' composition teaching because the above combined teachings would create

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the claimed composition having antioxidant and/or antimicrobial activity. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose..." Furthermore, the adjustment of other conventional working conditions (e.g. the form of the composition of placing well known food active ingredients within a soft gelatin capsule for easy absorption), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note, the intended use of the above claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Please note that the patentability of a product does not depend upon the method of production. If the product in a product by process claim is the same as or obvious

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from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process. (see, e.g. MPEP 2113).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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PRIMARY EXAMINER